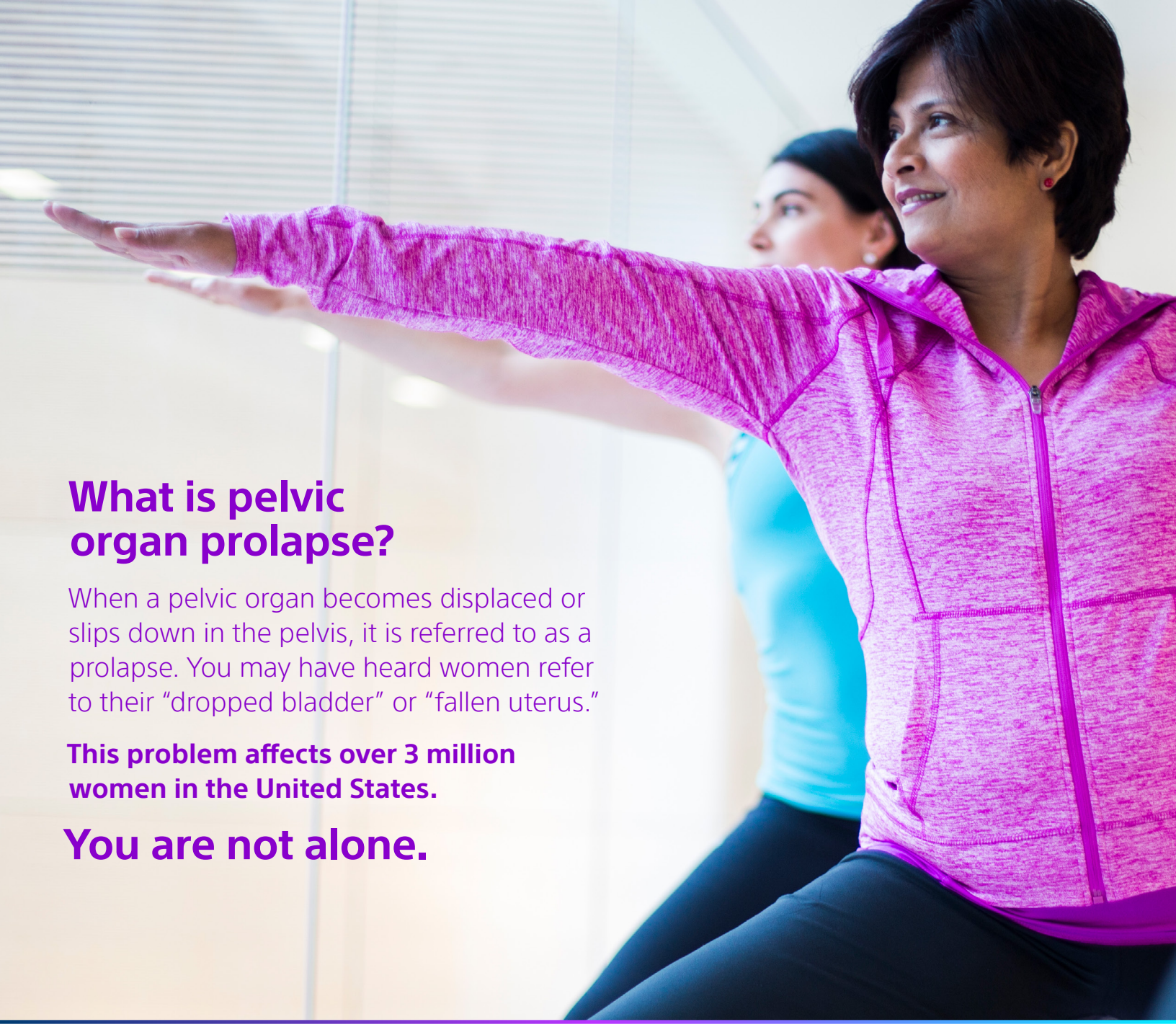
Your guide to understanding

Pelvic organ prolapse



What is pelvic organ prolapse?

When a pelvic organ becomes displaced or slips down in the pelvis, it is referred to as a prolapse. You may have heard women refer to their “dropped bladder” or “fallen uterus.”

This problem affects over 3 million women in the United States.

You are not alone.

What causes pelvic organ prolapse?

Pelvic organ prolapse (POP) occurs when the muscles or ligaments in your pelvic floor are stretched or become too weak to hold your organs in the correct position. When this happens, organs such as the bladder, rectum, and uterus can bulge (prolapse) into the vagina and sometimes past the vaginal opening. Potential causes of pelvic organ prolapse include: pregnancy, childbirth, and menopause.

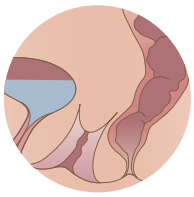
What are some of the symptoms?

Symptoms of pelvic organ prolapse can include:

- Pressure or discomfort in the vaginal or pelvic area, often made worse with physical activities such as prolonged standing, jogging or bicycling
- Diminished control in the bladder and/or the bowels
- Pain during intercourse
- A bulge near the opening of the vagina

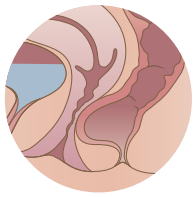
What are the types of pelvic organ prolapse?

Vaginal vault or uterine prolapse



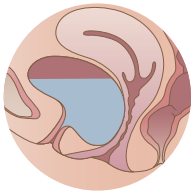
Vaginal vault prolapse occurs when the upper portion of the vagina (the apex) descends into the vaginal canal. If the uterus is present, this is called "uterine prolapse". When the apical prolapse becomes advanced, the bulge may become visible outside of the vaginal opening. The symptoms may include: pressure, pain, bladder infections and difficulty urinating.

Rectocele



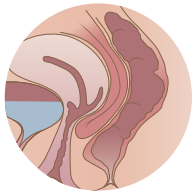
A rectocele forms when the lower vaginal wall loses its support, allowing the rectum to bulge into the vagina. This creates an extra pouch in the rectal tube. Larger rectoceles can bulge beyond the vaginal opening. Rectoceles may cause difficulty with bowel movements—including the need to strain more forcefully, a feeling of rectal fullness even after a bowel movement, increased fecal soiling and incontinence of stool or gas. Some patients have to push on the back of the vagina to have a bowel movement.

Cystocele

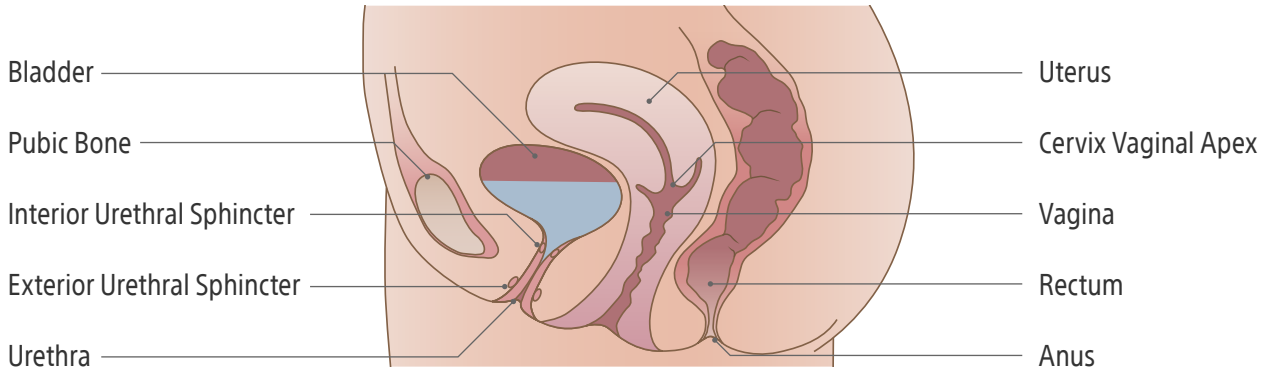


A cystocele forms when the upper vaginal wall loses its support and sinks downward. This allows the bladder, which is located above the vagina, to drop. When a cystocele becomes advanced, the bulge may become visible outside the vagina. The visible tissue is the weakened vaginal wall. The symptoms caused by cystoceles can include pressure, slowing of the urinary stream, overactive bladder and an inability to fully empty the bladder.

Enterocele



An enterocele typically forms when the small intestine bulges through the top of the vagina after a hysterectomy. In some women, the intestine may slide between the back of the vagina and the rectum as shown in this picture with a uterus. The symptoms can be vague, including a bearing down pressure in the pelvis and vagina, and perhaps a lower backache.



Normal anatomy

Your physician will be able to assess which type of pelvic organ prolapse you may have and review potential treatment options.

What are some treatment options?

You don't have to live with the symptoms of pelvic organ prolapse. Pelvic organ prolapse can be treated in several ways, depending on the exact nature and severity of your condition. The goal of these treatments is to restore prolapsed organs to their normal anatomical positions.

You and your physician may discuss:

Non-surgical options:

- Changes to your **diet** and fitness routine
- Use of a "**pessary**," which is a ring-like device designed to relieve symptoms when in place by holding up the vaginal walls. It is inserted vaginally and is removable.
- **Physical therapy** and pelvic floor exercises, such as Kegel exercises, designed to increase strength and maintain elasticity in the pelvic muscles

Surgical options:

- **Biologic graft** – A piece of biologic mesh is placed over the weakened connective tissue and sutured to correct the prolapsed area.
- **Sacrocolpopexy / sacrohysteropexy** – The physician uses an open, laparoscopic or robotic approach to attach a graft between the vaginal apex and the tailbone.
- **Native tissue repair** – The patient's own tissue is used and sutured to an existing pelvic structure in order to correct the prolapse.

Many surgical procedures have been developed for the correction of pelvic organ prolapse. Please consult your physician to discuss the treatment options, including the potential adverse reactions/ complications and post-operative care.

Frequently asked questions about surgical mesh

What is surgical mesh and what are the risks?

There are several surgical materials that could be used to facilitate your repair. These include a synthetic polypropylene mesh or biologic grafts made of dermis. Risk associated with implanting synthetic mesh in pelvic organ prolapse procedures can be found on the back of the brochure.

What should I expect after surgery?

Before your discharge from the hospital, you may be given a prescription for medication to relieve any discomfort you may experience. You will be instructed on how to care for your incision area. Most women recover well from surgery and find relief from their prolapse symptoms. Give yourself time to heal over the next six weeks. Avoid strenuous activity to allow for healing.

For more specific information on what to expect following any of the prolapse surgical options please consult with your physician.

Glossary

Apex – The top of the vagina (also known as vault).

Biologically derived graft – Tissue derived from human or animal source.

Cystocele – Condition in which weakness in pelvic support tissues causes the bladder to drop from its usual position down into the vagina.

Enterocele – Condition in which weakness in pelvic support tissues causes the small intestine to bulge downward into the vagina.

Laparoscopic surgery – A minimally invasive technique in which a procedure is performed through small incisions in the abdomen that are used to insert a camera and surgical instruments.

Minimally invasive surgery – A procedure that minimizes surgical incisions and reduces trauma to the body.

Native tissue repair – A type of surgical repair known as vaginal colporrhaphy, which uses sutures and the patient's own native vaginal tissue to repair the vaginal wall prolapse.

Open surgery – A procedure that requires an incision through the skin large enough for the surgeon to gain access to the structures they are operating upon.

Pelvic floor – A group of muscles that form at the base of the pelvis and support pelvic organs.

Pelvic floor reconstruction – The surgical repair of prolapse and incontinence. Surgical repair of pelvic support structures that can lead to pelvic organ prolapse and/or incontinence when weakened either via age-related changes or trauma.

Pelvic organ prolapse – A medical condition that occurs when normal support of the vagina is lost resulting in the "sagging" or "dropping" of pelvic organs.

Pessary – A removable plastic device that is inserted into the vagina to hold prolapsed organs back in place.

Rectocele – Condition in which weakness in pelvic support tissues causes the rectum to bulge into the vagina.

Stress urinary incontinence – The involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing or lifting.

Synthetic – Permanent material used to repair tissue damage, can be used to supplement a pelvic organ prolapse repair.

Transvaginal surgery – Surgery that is approached through an incision in the vagina.

Uterine prolapse – Condition in which weakness in pelvic support tissues and/or ligaments causes the uterus to drop from its usual position into and through the vaginal canal.

Vaginal vault prolapse – Condition in which weakness in pelvic support tissues and/or ligaments causes the vaginal vault (apex) to drop into or through the vaginal canal.

Vault – The top of the vagina in the absence of a uterus.

Important safety information

Please consult your physician to discuss the associated risk and complications for the specific surgical material you receive.

Potential adverse events, any of which may be ongoing, include but are not limited to: Abscess (swollen area within the body tissue, containing a buildup of pus), Adhesion formation (when a scar extends from within one area to another), Allergic reaction (hypersensitivity) to the implant, Bleeding, Bruising, Constipation, Dehiscence (opening of the incision after surgery), De novo detrusor instability (involuntary contraction of the bladder wall leading to an urge to urinate), Dyspareunia (pain during sexual intercourse) that may not resolve, Erosion into organs, exposure/extrusion into vagina (when the mesh goes through the vagina into other organs or surrounding tissue), Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Fistula formation (a hole/passage that develops through the wall of the organs) which may be acute or chronic, Foreign body reaction (body's inflammatory response to the implant) which may be acute or chronic, Granulation tissue formation (reddish connective tissue that forms on the surface when a wound is healing), Hematoma formation (a pool of blood under the skin/bruising), Hemorrhage (profuse bleeding), Infection, Inflammation (redness, heat, pain, or swelling at the surgical site as a result of the surgery) which may be acute or chronic, Injury to ureter (the duct that urine passes from the kidneys to the bladder), Mesh contracture (mesh shrinkage), Necrosis (death of living tissue in a small area), Nerve injury (injury to the nerve fiber), Organ perforation (a hole in or damage to these or other tissues that may happen during placement), Pain: pelvic, vaginal, groin/thigh, dyspareunia (which may become severe), Perforation or laceration of vessels, nerves, bladder, or bowel (a hole in or damage to these or other tissues that may happen during placement), Post-operative bowel obstruction (blockage that keeps food or liquid from passing through the small or large intestines), Prolapse/recurrent prolapse (complete failure of the procedure), Scarring/scar contracture (tightening of the scar), Sexual dysfunction (difficulty with sexual response, desire, orgasm, or pain); including the inability to have intercourse, Tissue contracture (tightening of the tissue), Vaginal shortening or stenosis which may result in Dyspareunia and/or Sexual dysfunction, Voiding dysfunction: incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention (involuntary leakage of urine or reduced or complete inability to empty the bladder).

The occurrence of one or more of these complications may require treatment or surgical intervention. In some instances, the complication may persist as a permanent condition after the surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

For Pelvic Organ Prolapse: Caution: U.S. Federal law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for transvaginal repair of pelvic organ prolapse.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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